AUG - 7 2001

K003281

510 (K) Summary of Safety and Effectiveness

Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Carol lauster

Device(s): plate, fixation, bone, screws

Classification: Class II

Device Product Code: HRS(plate) and HWC(screws)

Intended Use: The LactoSorb® RapidFlap™ is indicated for use in pediatric craniotomy flap fixation

Device Description: The LactoSorb® RapidFlap™ is comprised three parts, an inner plate, an outer plate and a central post. The inner plate consists of a circular disk through which the post is centrally extruded outwardly. The outer plate consists of a circular disk which a threaded hole to accept the post. The devices are assembled by hand to force the plates together capturing the bone. When applied, the plates tightly grip the bone flap, and provide rigid attachment and coplanar alignment to the surrounding bone.

The LactoSorb® RapidFlap™ is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years over 10 years in a ligating clip. LactoSorb® is a resorbable copolymer and synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids, which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

Potential Risks: 1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing and migration of the devices can occur as a result of excessive activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.

Substantial Equivalence: The LactoSorb® RapidFlap™ is substantially equivalent to the titanium RapidFlap™ K991029 and the LactoSorb® Trauma Plating System K971870.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Carol Lauster
Biomet, Incorporated
Airport Industrial Park
P.O. Box 587
Warsaw, India 46581-0587

Re: K003281
Trade/Device Name: LactoSorb® RapidFlap™
Regulation Number: 872.4760
Regulatory Class: II
Product Code: JEY
Dated: May 11, 2001
Received: May 14, 2001

Dear Ms. Lauster:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003281

DEVICE NAME: LactoSorb® RapidFlap™

INDICATIONS FOR USE:

The LactoSorb® RapidFlap™ is indicated for use in pediatric craniotomy flap fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003281